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No. 15-1195

In The

Supreme Court of the United States

AMGEN INC. AND AMGEN MANUFACTURING LIMITED, CROSS-PETITIONERS,

v.

SANDOZ INC.

ON CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

OPPOSITION TO THE CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Congress created an abbreviated regulatory pathway for the Food and Drug Administration ("FDA") to license "biosimilar" products—i.e., products that are "highly similar" to approved biological products. 42 U.S.C. § 262(i)(2). The BPCIA also created a carefully reticulated patent resolution regime for biosimilar applicants and the incumbent sellers of biological products, called reference product sponsors. As part of that regime, the statute provides that, within 20 days of the FDA's acceptance of a biosimilar application, the applicant "shall provide" a copy of the application to the reference product sponsor as the first step in a patent exchange and resolution scheme. *Id.* § 262(*l*)(2)(A). The BPCIA also expressly lays out a separate path for resolving any patent disputes in the event the applicant does not take that step: patent infringement litigation, with the scope and timing at the sole discretion of the sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

The question presented is:

When a biosimilar applicant does not provide its application to the reference product sponsor under 42 U.S.C. § 262(*l*)(2)(A), can the sponsor obtain an injunction under California law requiring the applicant to do so?

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, cross-respondent Sandoz Inc. states the following:

Sandoz Inc. is an indirect, wholly owned subsidiary of Novartis AG, which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

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INTRODUCTION

For Amgen to succeed on the state law claims at issue in its conditional cross-petition, Amgen would have to establish that the Federal Circuit erred *both* in its interpretation of the federal BPCIA statute *and* in its conclusions that Amgen's claims failed for separate reasons of California law. Amgen can establish neither. The court of appeals correctly concluded that (1) the BPCIA does not require a biosimilar applicant to disclose its application to the sponsor in all circumstances, and thus Amgen cannot establish the "unlawful" element of its state law claims, *and* (2) Amgen also failed to satisfy all the other required California law elements. The independent state law grounds make Amgen's conditional cross-petition a poor vehicle for review of the proper interpretation of the BPCIA's disclosure provisions. In contrast to the questions presented by Sandoz's petition—which challenge the Federal Circuit's creation of a *federal* injunctive remedy directly under the BPCIA to enforce its notice of commercial marketing provision—the cross-petition's arguments could support at most an advisory opinion on the meaning of the BPCIA's disclosure provisions, unless this Court were to take the unusual step of reaching questions of state law. For these reasons, the portion of the judgment challenged by Amgen does not warrant this Court's review.

As explained more fully in Sandoz's petition for a writ of certiorari, the BPCIA's patent exchange process includes a series of steps that an applicant or sponsor

"shall" take to start or continue the patent exchange process and a linked series of consequences that follow from not doing so. Amgen's conditional cross-petition involves the first such step: an applicant "shall provide" a copy of its biosimilar application to the sponsor within 20 days after the FDA accepts the application for review. 42 U.S.C. § 262(*l*)(2)(A). If the applicant does not do so, the BPCIA expressly lays out a separate path for resolving any patent disputes: patent infringement litigation, with the scope and timing at the sole discretion of the reference product sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii).

Sandoz chose not to provide its biosimilar application and instead to subject itself to the risk of immediate patent litigation. In response, Amgen filed suit, asserting (as relevant here) that Sandoz's decision to withhold its application was "unlawful" under the BPCIA. But in making these allegations, Amgen did not invoke any cause of action under the BPCIA itself or claim any right to an injunction under that federal statute. Instead, Amgen brought state law claims, alleging that Sandoz's alleged violations of the BPCIA provided bases for state law injunctive remedies under (1) California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code § 17200 *et seq.*, and (2) the common law of conversion.

The Federal Circuit rejected Amgen's state law claims relating to disclosure of the biosimilar application, for two independent reasons. ***First***, the court of appeals correctly interpreted the relevant portion of

the BPCIA. It held that the BPCIA expressly contemplates that an applicant may choose to withhold its application and that the statute lays out a specific path for resolution of any patent disputes in that situation. Correctly recognizing that there is nothing "unlawful" about taking an option provided by a statute, the court of appeals held that Sandoz did not act unlawfully by withholding its application. And because unlawful action was a required element of each of Amgen's California causes of action, both claims failed on that basis.

Second, the court of appeals also correctly held that each claim failed for independent state law reasons: the California UCL claim because that statute provides no remedy for alleged violations of schemes that make their own remedies expressly exclusive, and the California conversion claim because Amgen did not establish an exclusive right to its approved license. Amgen's conditional cross-petition thus presents a singularly poor vehicle for review. To obtain reversal of the Federal Circuit's judgment, Amgen would have to persuade this Court not only that the court of appeals' interpretation of the BPCIA was wrong (which Amgen cannot do), but *also* that the court's interpretation of separate elements of California UCL and conversion law was erroneous. This Court does not typically grant certiorari to resolve state law questions, and Amgen does not even attempt to explain why the Court should take that extraordinary step here.

By contrast, the portion of the Federal Circuit's judgment challenged by Sandoz's certiorari petition

presents none of these complications. The court of appeals held that Amgen has a *federal* cause of action to enforce the court of appeals' interpretation of the BPCIA's notice of commercial marketing provision by means of a *federal* injunctive remedy—which the Federal Circuit issued. Sandoz's petition thus asks this Court to review the grant of a federal remedy for what the Federal Circuit held to be a violation of federal law.

Amgen is therefore wrong in asserting that if the Court grants Sandoz's petition it also should grant Amgen's conditional cross-petition. Each petition must meet this Court's certiorari standards on its own, and Amgen's does not. Moreover, Amgen's choice to file only a conditional cross-petition—as well as the lack of any amici supporting it—suggests its question presented is not sufficiently important to warrant this Court's consideration.

The conditional cross-petition should be denied.

JURISDICTION

The judgment of the court of appeals was entered on July 21, 2015, not July 1, 2015, as stated in the conditional cross-petition. Sandoz is otherwise satisfied with the statement of jurisdiction in the conditional cross-petition.

STATEMENT

A. Statutory Background

Sandoz's petition includes a detailed description of the BPCIA, which will not be repeated in full here. 15-1039 Pet. 8-11. Amgen's conditional cross-petition

involves the first step of the BPCIA's patent exchange process, in which the applicant "shall provide" a copy of its biosimilar application to the sponsor within 20 days after the FDA accepts the application for review. 42 U.S.C. § 262(*l*)(2)(A). Throughout the BPCIA, Congress spelled out the actions the applicant or sponsor "shall" take to start and continue the process. In later steps, the parties exchange lists of patents for which they believe a claim of patent infringement could reasonably be asserted; exchange their respective positions on infringement, validity, and enforceability; and negotiate regarding the patents for which an immediate infringement action may be brought. *Id.* § 262(*l*)(3)-(5).

Congress also spelled out exactly what happens if a party declines to follow a particular step in the information exchange process. As particularly relevant here, if the applicant does not take the first step (i.e., provide its biosimilar application to the sponsor within 20 days of its acceptance by the FDA), the BPCIA expressly lays out a separate path for resolving any patent disputes: patent litigation, with the scope and timing at the sole discretion of the reference product sponsor. *Id.* § 262(*l*)(9)(C); 35 U.S.C. § 271(e)(2)(C)(ii). Even if the patent exchange process is initiated, and regardless of whether it is completed, the end result is that the reference product sponsor or the applicant can bring a patent suit. The contours of that suit are determined by the actions that the parties did or did not take in the information exchange process. 35 U.S.C. § 271(e)(2)(C), (4), (6); 42 U.S.C. § 262(*l*)(6), (9)(A)-(B).

B. Factual Background

1. Sandoz's biosimilar application

On July 7, 2014, the FDA accepted for review Sandoz's application for biosimilar filgrastim. Pet. App. 8a.[1] The next day, Sandoz notified Amgen that Sandoz had filed the application and that Sandoz expected FDA approval in the first half of 2015. *Ibid.*

In light of Amgen's public statements in filings with the Securities and Exchange Commission that it had no material, unexpired patents for filgrastim, Sandoz determined that subjecting itself to an immediate patent suit was the quickest path to resolution of any patent claims. CA JA A915, A960, A1495-A1497. On July 25, 2014, Sandoz therefore informed Amgen that it had "opted not to provide Amgen with Sandoz's biosimilar application within 20 days of the FDA's notification of acceptance" and that the BPCIA thus entitled Amgen to bring a declaratory judgment action for patent infringement against Sandoz. Pet. App. 8a; *see* 42 U.S.C. § 262(*l*)(9)(C). Amgen thus had the ability to sue to enforce any patent rights months earlier than would have been the case if Sandoz had participated in the patent exchange process, which "could take up to 230 days." Pet. App. 72a.

2. Proceedings in district court

a. Although Amgen could have brought a declaratory judgment action for artificial infringement as

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[1] All appendix citations are to the petition appendix in No. 15-1039.

early as July 28, 2014, it delayed bringing suit until October 2014, when it asserted three claims. Pet. App. 9a.

First, Amgen brought a claim under California's UCL statute, which provides a cause of action against "any unlawful, unfair or fraudulent business act or practice." Pet. App. 26a. Amgen alleged that Sandoz committed "unlawful" acts for purposes of the UCL by violating the BPCIA. Pet. App. 9a. As relevant to Amgen's conditional cross-petition, Amgen alleged that Sandoz violated the BPCIA by not providing Amgen its application within 20 days of the FDA's acceptance of Sandoz's application. *Ibid.* Amgen also alleged that Sandoz acted unlawfully by giving an allegedly premature, ineffective notice of commercial marketing before FDA approval, *ibid.*—the claim at issue in Sandoz's petition for a writ of certiorari. *See* 42 U.S.C. § 262(*l*)(8)(A).

Second, Amgen brought a state law claim for conversion, alleging that Sandoz wrongfully used Amgen's approved license for Neupogen® without complying with the BPCIA. Pet. App. 9a.

Third, expressly invoking the recourse provided by the BPCIA, 42 U.S.C. § 262(*l*)(9)(C), Amgen brought a claim for artificial infringement of Amgen's U.S. Patent No. 6,162,427 ("'427 patent"), which claims a method of treating a patient using filgrastim. Pet. App. 9a; *see* 15-1039 Pet. 9 (discussing BPCIA's creation of artificial acts of infringement to promote early resolution of patent disputes). Amgen, however, did not seek (and

still has not sought) an injunction based on purported patent infringement.

Sandoz counterclaimed, seeking declaratory judgments concerning the correct interpretation of the BPCIA in order to "resolve Amgen's claims for conversion and violation of California's Unfair Competition Law," and declaratory judgments for non-infringement and invalidity of the '427 patent. Pet. App. 9a; *see* CA JA A281.

b. On March 6, 2015, the FDA approved Sandoz's biosimilar filgrastim product Zarxio®, the first biosimilar approved under the BPCIA. Pet. App. 8a-9a. Sandoz provided Amgen a "further notice of commercial marketing" on that same day. Pet. App. 9a.

c. Later in March 2015, the district court denied Amgen's motions for judgment on the pleadings and for a preliminary injunction and granted Sandoz's motion for judgment on Amgen's state law claims and Sandoz's BPCIA counterclaims. Pet. App. 56a-84a.

The district court concluded that it was lawful for Sandoz not to provide Amgen its biosimilar application within 20 days of acceptance by the FDA. Pet. App. 68a-73a. The court noted that Section 262(*l*)(2)(A) states that an applicant "shall provide" a copy of its application to the reference product sponsor and that the patent exchange provisions often "use the word 'shall' to describe the parties' obligations under [subsection (*l*)'s] prescribed procedures." Pet. App. 69a. In context, however, the court explained that these provisions "demand that, if both parties wish to take

advantage of [the BPCIA's] disclosure procedures, then they 'shall' follow the prescribed procedures." *Ibid.* At the same time, the statute "contemplate[s] the scenario in which an applicant does not comply at all with disclosure procedures" by "allow[ing] the reference product sponsor to commence patent litigation immediately." Pet. App. 69a-70a.

The district court noted that Congress did not "remain silent" on remedies: "it expressly directed reference product sponsors to commence patent infringement litigation in the event of an applicant's noncompliance." Pet. App. 71a. "It is therefore evident that Congress intended merely to encourage use of the statute's dispute resolution process in favor of litigation, where practicable, with the carrot of a safe harbor for applicants who otherwise would remain vulnerable to suit." *Ibid.* The court observed that the statute "contains no stick to force compliance in all instances" and that "Amgen does not identify any basis to impute one." *Ibid.* "The effect of Amgen's position—that Congress intended for sponsors to resort to state laws to enforce mandatory provisions in a federal statute and collect remedies for their violation, in addition to exacting the consequences written expressly into the legislation itself—is unworkable." Pet. App. 78a-79a.[2]

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[2] The district court also concluded that it was lawful for Sandoz to provide its 180-day notice of commercial marketing before FDA approval, meaning that Sandoz's July 2014 notice was effective. Pet. App. 73a-76a. That issue is presented in Sandoz's petition for a writ of certiorari.

d. The district court entered final judgment under Federal Rule of Civil Procedure 54(b) on Amgen's state law claims and Sandoz's BPCIA counterclaims. Pet. App. 11a. The court granted the parties' joint request to stay all other proceedings, including Amgen's patent infringement claim and Sandoz's patent counterclaims. *Ibid.*

3. Proceedings in the Federal Circuit

a. In May 2015, the Federal Circuit issued an injunction pending appeal, precluding Sandoz from marketing, selling, offering for sale, or importing into the United States its FDA-approved Zarxio® product. Pet. App. 31a; CAFC Dkt. No. 105.

b. In July 2015, a fractured Federal Circuit panel affirmed the dismissal of Amgen's state law claims for unfair competition and conversion, vacated the judgment on Sandoz's counterclaims, and remanded. Pet. App. 1a-55a. The court also extended the injunction pending appeal through September 2, 2015—180 days from when the FDA approved Sandoz's filgrastim and Sandoz provided its second notice of commercial marketing. Pet. App. 31a.

On the issue raised by Amgen's cross-petition, a majority of the court (Judge Lourie joined by Judge Chen) held that Sandoz "did not violate the BPCIA by not disclosing its [application] and the manufacturing information by the statutory deadline" because in doing so Sandoz "took a path expressly contemplated by the BPCIA." Pet. App. 18a; *see also* Pet. App. 15a (noting that "the 'shall' provision in paragraph (*l*)(2)(A)

cannot be read in isolation"). As the court explained, the BPCIA "specifically sets forth the consequence for such failure" to provide the application: the sponsor "may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)," but the applicant remains barred from bring its own declaratory judgment action. Pet. App. 15a-17a.

Indeed, the court of appeals observed that withholding the application and information "is precisely an act of infringement under § 271(e)(2)(C)(ii), for which § 271(e)(4) provides the 'only remedies.'" Pet. App. 18a. The statute "has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A)." Pet. App. 15a-16a. Both provisions triggered by an applicant's failure to disclose its application "are premised on a claim of patent infringement, and the BPCIA does not specify any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." Pet. App. 17a.

The court of appeals noted that Amgen's UCL claim was "based solely" on that statute's "'unlawful' prong, which requires a showing that Sandoz acted unlawfully by violating another law, here, according to Amgen, the BPCIA." Pet. App. 26a-27a. The claim failed because, as the court had held, "Sandoz did not violate the BPCIA by not disclosing its [application] and the manufacturing information according to § 262(*l*)(2)(A)." Pet. App. 27a.

The court also explained that "[u]nder California law, UCL remedies are not available when the underlying law expressly provides that the remedies in that law are exclusive." Pet. App. 27a (citing Cal. Bus. & Prof. Code § 17205; *Loeffler v. Target Corp.*, 324 P.3d 50, 76 (Cal. 2014)). The court held that Amgen's claim failed for this reason as well: "35 U.S.C. § 271(e)(4) provides 'the only remedies which may be granted by a court' for the alleged violation" of withholding an application. Pet. App. 27a; *accord* Sandoz CA Br. 54-56.

The court likewise held that Amgen's conversion claim failed on two independent grounds—one based on the BPCIA and one based on state law. Pet. App. 28a-29a. First, because "the BPCIA explicitly contemplates that a subjection (k) applicant might not disclose its [application] and the manufacturing information by the statutory deadline, and provides that the [sponsor] may sue for patent infringement, which Amgen has done, Amgen thus failed to show a 'wrongful act,'" as required by the conversion cause of action. *Ibid.* Second, given the expiration of Amgen's period of exclusivity under the BPCIA, Amgen "fail[ed] to show that it has an *exclusive* right to possession of its approved license on Neupogen to sustain its claim of conversion under California law." Pet. App. 29a; *accord* Sandoz CA Br. 57.

Judge Newman dissented from this part of the decision. Pet. App. 35a-42a (Newman, J., dissenting).[3]

c. Sandoz launched its biosimilar filgrastim product Zarxio® in the United States on September 3, 2015.

d. Both Sandoz and Amgen filed petitions for rehearing en banc. Pet. App. 85a-86a. Sandoz's rehearing petition (addressing the notice of commercial marketing provision that is the subject of Sandoz's petition for a writ of certiorari) was supported by multiple amici stressing the importance of that issue: The Biosimilars Council (CAFC Dkt. No. 139), Hospira, Inc., Celltrion Healthcare Co., Ltd., and Celltrion, Inc. (CAFC Dkt. No. 140); and Mylan Inc. (CAFC Dkt. No. 150). Amgen's rehearing petition (addressing the application disclosure issue that is the subject of Amgen's conditional cross-petition) drew no amicus support. The Federal Circuit denied both petitions for en banc review. Pet. App. 85a-86a.

e. The Federal Circuit remanded to the district court, which lifted the stay on Amgen's patent claims

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[3] The Federal Circuit also interpreted the BPCIA's "[n]otice of commercial marketing" provision to mean that the "applicant may only give effective notice of commercial marketing *after* the FDA has licensed its product." Pet. App. 20a (emphasis added). The court further ruled that this interpretation could be enforced by issuance of an injunction under federal law, and barred Sandoz from marketing its biosimilar "before 180 days from March 6, 2015." Pet. App. 26a; *see* Pet. App. 31a. Those portions of the Federal Circuit's judgment are at issue in Sandoz's petition for a writ of certiorari.

and Sandoz's patent counterclaims. Amgen still has sought no patent-based injunction.

REASONS FOR DENYING THE CONDITIONAL CROSS-PETITION

The court of appeals concluded both that Sandoz did not violate the BPCIA by withholding its application and that Amgen's UCL and conversion claims failed for independent state law reasons. Those determinations do not warrant this Court's review. The Federal Circuit's interpretation of the BPCIA provisions challenged by Amgen was correct, and the necessity of resolving state law questions to reverse that portion of the judgment makes the conditional cross-petition a poor vehicle for review.

A. The Court Of Appeals Correctly Affirmed Dismissal Of Amgen's State Law UCL And Conversion Claims Because It Was Lawful For Sandoz Not To Provide Its Application Under Section 262(*l*)(2)(A)

The court of appeals correctly affirmed dismissal of Amgen's California UCL and conversion claims. Both claims require as one element that Sandoz have acted unlawfully when it withheld its application from Amgen. Pet. App. 26a-27a, 28a-29a. The court of appeals correctly held that Amgen could not satisfy this element. There was nothing unlawful in Sandoz's electing to take a path expressly laid out by the BPCIA.

1. The BPCIA's carefully reticulated regime expressly contemplates the patent resolution path taken by Sandoz

The Federal Circuit correctly concluded that "Sandoz did not violate the BPCIA by not disclosing its [application] and the manufacturing information according to § 262(*l*)(2)(A)." Pet. App. 27a. "Sandoz took a path expressly contemplated" by the BPCIA: withholding its application and subjecting itself to patent litigation at a time and scope of the sponsor's choosing—a suit that Amgen already has brought. *Ibid.*

The BPCIA created a carefully reticulated regime to allow patent disputes to commence before FDA approval, facilitating their resolution as quickly as possible. One route to the pre-approval patent infringement action created by the BPCIA is to complete the statutory patent exchange process. As a condition precedent to starting the process, the applicant "shall provide to the reference product sponsor a copy of the application submitted" within 20 days of the FDA's acceptance of the application. 42 U.S.C. § 262(*l*)(2)(A). But as the court of appeals recognized (Pet. App. 15a-18a), the BPCIA expressly contemplates that an applicant might not provide its application under subsection (*l*)(2)(A). *See* 42 U.S.C. § 262(*l*)(9)(C). In that event, the patent exchange process does not happen, and the BPCIA authorizes the sponsor to file suit immediately based on that act of artificial infringement, as Amgen has done. *See* 35 U.S.C. § 271(e)(2)(C)(ii); 42 U.S.C. § 262(*l*)(9)(C). As the Federal Circuit explained, "[o]nce the [sponsor] brings an infringement suit under

those two provisions, it can access the required information through discovery," as Amgen also has done. Pet. App. 17a.

Rather than allowing either party to compel compliance with any particular step in the patent exchange process, the BPCIA provides both parties incentives to participate. *See* Pet. App. 71a. The applicant that does not trigger the patent exchange process loses its ability to impact the timing of an artificial infringement suit by the sponsor, 42 U.S.C. § 262(*l*)(9)(A), and it loses the control it otherwise would have over which patents, or how many, the sponsor can assert. *Compare id.* § 262(*l*)(9)(C), *with id.* § 262(*l*)(3)-(5). Where the patent exchange process has not been triggered, the sponsor also decides whether to delay suit until after FDA approval, forcing the applicant to launch at risk. An applicant may nevertheless choose this path if the applicant seeks a quick resolution, believes that no unexpired, relevant patents will remain after the exclusivity period expires, and/or has concerns about turning over its application without a court protective order. *See* Pet. App. 72a.

In light of the BPCIA's integrated patent resolution regime, the court of appeals correctly concluded that "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation." Pet. App. 15a. Despite many instances of "shall," the BPCIA provides multiple points at which the sponsor or the applicant may exit the patent exchange process, and the statute delineates the effect of that choice on the scope and timing of a patent suit. In particular, as the court of appeals correctly

concluded, the statute "specifically sets forth the consequence" when an applicant does not provide its application under subsection (*l*)(2)(A): "the [sponsor] may bring an infringement action under 42 U.S.C. § 262(*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii)." Pet. App. 15a. Those provisions "indicate that 'shall' in paragraph (*l*)(2)(A) does not mean 'must'" in all circumstances. *Ibid.* And "mandating compliance with paragraph (*l*)(2)(A) in all circumstances would render paragraph (*l*)(9)(C) and 35 U.S.C. § 271(e)(2)(C)(ii) superfluous." Pet. App. 17a. The court of appeals correctly concluded that taking "a path expressly contemplated by the BPCIA" cannot violate the Act. Pet. App. 18a.

Accordingly, the court of appeals concluded that Sandoz's withholding of its application was lawful under the BPCIA and therefore could not be the basis for a UCL or conversion cause of action. Pet. App. 27a (UCL), 28a-29a (conversion).

2. *None of Amgen's objections to the court of appeals' analysis has merit*

All of Amgen's criticisms of the court of appeals' analysis fail.

a. Amgen's principal submission is that the "plain text of subparagraph 262(*l*)(2)(A) requires the [a]pplicant to provide its [application] and manufacturing information to the [s]ponsor" because that provision uses the word "shall," which is "generally mandatory." Cross-Pet. 26. But as this Court recently emphasized, an interpretation of a statutory phrase

that is "plausible in the abstract" fails when it is "ultimately inconsistent with both the text and context of the statute as a whole." *Sturgeon v. Frost*, 136 S. Ct. 1061, 1070 (2016); *see FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme." (internal quotation omitted)). Indeed, Amgen's argument rests almost entirely on one word ("shall") and therefore violates the rule that words in statutes are not to be read "in isolation" but instead "'in context [since] a phrase gathers meaning from the words around it.'" *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (quoting *Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 596 (2004)) (alteration in *Hibbs*).

Read in its proper context, the "shall" in Section 262(*l*)(2)(A) creates only a mandatory condition precedent. It specifies an action that an applicant *must* take to proceed to the next step of the patent exchange process: *if* an applicant wishes to engage in the patent exchange process, it "shall" timely provide its application to the sponsor. 42 U.S.C. § 262(*l*)(2)(A); *see* Pet. App. 69a. But when the applicant does not satisfy that condition, the statute shifts the parties to a different patent resolution track. "*If* a subsection (k) applicant fails to provide [its] application," 42 U.S.C. § 262(*l*)(9)(C) (emphasis added), the sponsor immediately gains standing to commence a declaratory judgment action under the BPCIA's amendments to the Patent Act, which make that precise failure an act of

artificial infringement. Pet. App. 15a-17a; 35 U.S.C. § 271(e)(2)(C)(ii).

Section 262(*l*)(6) confirms that the word "shall" as used in subsection (*l*) does not denote a requirement that is mandatory in all circumstances. Subsection (*l*)(6) provides that at the end of the patent exchange process, "the reference product sponsor *shall* bring an action for patent infringement" on specified patents within 30 days. 42 U.S.C. § 262(*l*)(6) (emphasis added). If Amgen were correct that "shall" in subsection (*l*) means mandatory in all circumstances, then a sponsor that failed to file an immediate suit for artificial infringement would be "violating" subsection (*l*)(6). *See Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007) ("A standard principle of statutory construction provides that identical words and phrases within the same statute should normally be given the same meaning."). It is not rational to believe that Congress made it "unlawful" for a private party to opt not to sue another private party.

Instead, the BPCIA provides incentives for the sponsor to bring an immediate suit, paired with consequences if it does not. Thus, just as with the "shall" provision in subsection (*l*)(2), the requirement that a sponsor "shall" sue within a specified time frame is a condition precedent to other statutory benefits, namely, the availability of the full patent law remedies provided in Section 271(e). 35 U.S.C. § 271(e)(4), (6)(B). Just as in subsection (*l*)(2), the BPCIA expressly envisions that a sponsor might not sue until "*after* the

expiration of the 30-day period" and provides consequences in that event, namely, limiting a sponsor's available remedies. *Id.* § 271(e)(6)(A)(ii)(I), (B) (emphasis added). That same "if/then" structure is present throughout subsection (*l*).

b. Amgen also contends that its interpretation of the "shall" in subsection (*l*)(2) as always mandatory is "confirm[ed]" by the BPCIA's "juxtaposition" of "shall" with "may"; the statute's description of the application and manufacturing information as "required"; and its reference "to non-provision of that information as a 'failure.'" Cross-Pet. 26-27. That is incorrect.

Subsection (*l*)(2) uses "shall" and "may" to distinguish between (1) the information that "shall" be turned over as a mandatory condition precedent to participating in the patent exchange process, 42 U.S.C. § 262(*l*)(2)(A), and (2) the additional information that "may" be optionally provided to the sponsor but is not a condition precedent to proceeding to the next step of the patent exchange process, *id.* § 262(*l*)(2)(B). Similarly, the statute uses the word "required" to distinguish between the same two types of information—the information required by the condition precedent in subsection (*l*)(2)(A) as opposed to any additional information that might be optionally disclosed under subsection (*l*)(2)(B). *See id.* § 262(*l*)(1)(B)(i); *id.* § 262(*l*)(9)(A), (C).

Nor does the BPCIA's description of the non-provision of the subsection (*l*)(2)(A) information as a "fail[ure]" mean that providing that information is

mandatory in all circumstances or that not providing that information is somehow wrongful. *See id.* § 262(*l*)(9)(C). Indeed, the statute uses "fails to provide the application" and "application not provided" interchangeably. *Ibid.* ("Subsection (k) application not provided—If a subsection (k) applicant fails to provide the application * * *"). And the BPCIA elsewhere uses "fail[]" when there plainly is no duty. Subsection (*l*)(4)(B) is titled "Failure to reach agreement" and discusses what happens if the parties "fail to agree on a final and complete list" of patents to litigate. *Id.* § 262(*l*)(4)(B). Yet despite the use of "fail," there is no obligation to agree and certainly no means to compel agreement.

In short, "shall" in the context of Section 262(*l*) simply means that there is a statutorily defined consequence for "failure" to take a particular action.

c. Amgen posits that if an applicant does not initiate the patent exchange process by providing its application and manufacturing information under subsection (*l*)(2)(A), a sponsor would not know "which, if any, of its manufacturing patents would be infringed by the [a]pplicant's manufacturing processes." Cross-Pet. 28. This policy objection is baseless and provides no reason to disregard the BPCIA's text and structure. Competitors rarely have access to each other's confidential manufacturing processes before litigating. But they regularly file infringement suits based on patents they reasonably believe are infringed after diligent investigation, such as pre-suit letters seeking information about manufacturing processes.

If there is no response, the patentee can file suit without violating Federal Rule of Civil Procedure 11. *See Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1363-65 (Fed. Cir. 2000). Then, after suing, patentees use discovery to learn detailed information and amend their complaint if necessary. Pet. App. 17a.

d. Amgen contends that the Federal Circuit's ruling "upend[s]" the "regulatory balance" because the injunction authorized by 35 U.S.C. § 271(e)(4)(D) is not available when an applicant does not initiate the patent exchange process by disclosing its application. Cross-Pet. 30. Amgen contends this provision "creates a mandatory permanent injunction." *Id.* at 29. But Amgen cites no support for that characterization, which runs counter to this Court's consistent rejection of invitations to read statutory provisions as requiring the automatic issuance of injunctions without examination of "traditional equitable considerations." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392-93 (2006).

In any event, the Section 271(e)(4)(D) injunction is available only in narrowly defined circumstances that will rarely occur: when there is patent litigation that proceeds to a final decision in the Federal Circuit before the reference product's statutory period of exclusivity expires. *See* 35 U.S.C. § 271(e)(4)(D) (cross-referencing 42 U.S.C. § 262(k)(6) & (7)); *see* 42 U.S.C. § 262(*l*)(5)(B)(ii)(II). Amgen's period of exclusivity expired long ago, so it would not have had access to this provision even if Sandoz had provided its application. Moreover, the statute separately provides sponsors

with the ability to obtain an injunction under 35 U.S.C. § 271(e)(4)(B)—without any condition precedent related to the patent exchange process. There is thus no imbalance created by the Federal Circuit's interpretation.

e. Amgen's discussion of unenacted pre-BPCIA legislation sheds no light on the meaning of the BPCIA. *Cf.* Cross-Pet. 30-31 (citing *Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001)). Here, the Federal Circuit's interpretation of the BPCIA does not depend on "read[ing] back into the Act" a word or phrase that Congress "deleted" during consideration of the actual bill that became the BPCIA. *Chickasaw Nation*, 534 U.S. at 93. Instead, Amgen invokes bills from previous Congresses that went nowhere and that proposed different biosimilar schemes. And Amgen cites nothing from the legislative history of the BPCIA itself attributing any significance to the differences Amgen highlights. *See Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989) (observing that "mute intermediate legislative maneuvers are not reliable indicators of congressional intent") (quotation marks and citation omitted).

f. Finally, contrary to Amgen's suggestion, the fact that both the petition and the conditional cross-petition present questions related to the interpretation of the BPCIA is no reason to grant review of the cross-petition. The cross-petition must itself satisfy this Court's certiorari standards. It does not.

B. The Court Of Appeals Correctly Affirmed Dismissal Of Amgen's California UCL And Conversion Claims For State Law Reasons Independent Of Whether Withholding The Application Was "Unlawful"

In addition to concluding that Sandoz had not violated the BPCIA by withholding its application, the court of appeals affirmed the judgment dismissing Amgen's complaint on alternative state law grounds. Those bases for dismissal independently support the judgment below, yet Amgen's cross-petition does not even acknowledge them, much less demonstrate that they warrant this Court's review. They do not. *See The Wharf (Holdings) Ltd. v. United Int'l Holdings, Inc.*, 532 U.S. 588, 596 (2001) (noting that the Court does not "ordinarily" consider "state-law issue[s]"); *see generally* Eugene Gressman et al., *Supreme Court Practice* 261 (9th ed. 2007) (discussing this Court's "strong reluctance" to review questions of state law).

As noted above, the only causes of action on appeal were asserted under California law. Amgen acknowledges that it "did not assert a private right of action under the BPCIA." Amgen 15-1039 Br. in Opp. 28. Instead, Amgen contended that Sandoz's alleged failures to comply with the BPCIA were "unlawful" for purposes of the UCL and that the UCL authorized Amgen to secure an injunction. Pet. App. 9a-10a. Amgen also asserted a state law claim for conversion based on Sandoz's use of "Amgen's approved license on Neupogen by filing an [application] referencing Neupogen

but refusing to provide Amgen the benefits to which it is entitled under § 262(*l*)." Pet. App. 28a-29a.

The court of appeals affirmed dismissal of all of Amgen's state law claims—with respect to both the notice of commercial marketing (the subject of Sandoz's certiorari petition) and Sandoz's withholding of its application (the subject of Amgen's cross-petition). Pet. App. 26a, 31a. Yet with respect to Amgen's claim regarding the notice of commercial marketing provision, the court of appeals nonetheless fashioned a cause of action and nationwide injunctive remedy as a matter of federal law. Pet. App. 31a; 15-1039 Pet. 18-19, 31-35.[4] Because the Federal Circuit created a federal cause of action to enforce Amgen's interpretation of the notice of commercial marketing provision, that portion of its decision squarely presents the federal question posed by Sandoz's certiorari petition. *See* 15-1039 Pet. 31-36.

By contrast, the court of appeals created no federal remedy with respect to Amgen's claim based on Sandoz's withholding of its application. Instead, the court rejected those UCL and conversion claims not only because Sandoz's withholding of its application was lawful under the BPCIA (*supra* Part A), but also

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[4] In contrast to the nationwide injunction the court of appeals granted Amgen as a matter of federal law on the notice of commercial marketing provision, a California UCL injunction would have necessarily been limited to California. *See Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1359-60 (Fed. Cir. 2013), *cert. denied*, 135 S. Ct. 2886 (2015).

because those claims suffered from independent state law defects.

1. California law bars a UCL remedy for Amgen because of the BPCIA's express exclusive remedies provision

California law provides that UCL remedies are not permitted when the underlying law "expressly provide[s]" that the remedies in that law are exclusive. Cal. Bus. & Prof. Code § 17205; *see Loeffler*, 324 P.3d at 76 (action under UCL can be barred where "another statutory scheme provides the exclusive means for resolving disputes"). For example, when an underlying statute provides that "its remedies 'are the exclusive remedies available,'" additional remedies under the UCL are foreclosed. *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 950 P.2d 1086, 1099 (Cal. 1998) (quoting Cal. Civ. Code § 7104).

Here, as noted above, the BPCIA's amendments to the Patent Act expressly provide that patent remedies "are the *only* remedies which may be granted by a court" for the failure to provide a biosimilar application. 35 U.S.C. § 271(e)(4) (emphasis added). Accordingly, even assuming that Amgen's interpretation of the BPCIA were correct and Sandoz violated it by not providing its application, the court of appeals correctly held that additional UCL remedies for that "violation" are unavailable as a matter of California law. *See* Pet. App. 27a; *see also* Pet. App. 67a n.4 (district court's characterization of Amgen's contention that it could

look for remedies beyond the BPCIA's "self-contained statutory scheme" as "untenable").

Specifically, Section 271(e)(2)(C)(ii) makes the very conduct about which Amgen complains—an applicant *both* submitting a biosimilar application *and* failing to provide the application and manufacturing information to the sponsor under subsection (*l*)(2)(A)—an act of artificial infringement under paragraph (2). 35 U.S.C. § 271(e)(2)(C)(ii). As the Federal Circuit explained, "35 U.S.C. § 271(e)(4) provides 'the *only* remedies which may be granted by a court for an act of infringement described in paragraph (2).'" Pet. App. 18a (emphasis by court of appeals). Those remedies are patent-based remedies, and the BPCIA does not include "any non-patent-based remedies for a failure to comply with paragraph (*l*)(2)(A)." Pet. App. 17a.

To try to avoid the exclusivity of the remedies in Section 271(e)(4), Amgen discusses in isolation the declaratory judgment actions referred to in subsection (*l*)(9). Amgen observes that (unlike Section 271(e)(4)), subsection (*l*)(9) includes no express "only remedies" language. Cross-Pet. 34. As an initial matter, Amgen fails entirely to address the dispositive question: whether *as a matter of California law* the statement of exclusivity in Section 271(e)(4) would bar additional UCL remedies. Pet. App. 27a. Amgen's cross-petition should be denied on that basis alone.

In any event, Amgen's effort to separate the two BPCIA sections fails. Amgen addresses the declaratory judgment provisions (Cross-Pet. 32-35) independently from the artificial infringement provisions (*id.* at 35-38), arguing that neither standing alone is "remedial" or "an exclusive remedy." But these provisions cannot be considered in isolation. Without the BPCIA's amendments to the Patent Act creating an artificial act of infringement, the sponsor would have no action under the Declaratory Judgment Act (or any other statute) based on an applicant's withholding of its application. That act of artificial infringement (with its exclusive remedies limitation) is what enables the sponsor to bring a declaratory judgment suit under subsection (*l*)(9). *See Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344, 1351 (Fed. Cir. 2004).

Amgen also observes that Section 262(*l*)(9)(C) does not specifically refer to a declaratory judgment action over process patents. Cross-Pet. 34. Again, Amgen errs by reading the provision in isolation. As the court of appeals noted, 35 U.S.C. § 271(e)(2)(C)(ii) expressly "allows the [sponsor] to assert process patents." Pet. App. 16a n.3.

Amgen next asserts that "[f]ailing to provide the [application] and manufacturing information is *not* an act of infringement" under Section 271(e), asserting that the court of appeals "read[] a limitation into infringement under section 271(e)(2)(C)(ii)." Cross-Pet. 37. But that limitation is in the text of the provision itself:

> It shall be an act of infringement to submit— * * * if the applicant for the application *fails to provide the application and information required under section [262](l)(2)(A)* of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section [262](*l*)(3)(A)(i) of such Act.

35 U.S.C. § 271(e)(2)(C)(ii) (emphasis added). If there is no such failure, there is no artificial infringement under Section 271(e)(2)(C)(ii).

Amgen also contends that the artificial infringement action authorized by 35 U.S.C. § 271(e)(2)(C)(ii) is not "remedial." Cross-Pet. 35. Congress expressly disagrees. It identified that provision as a "*remed[y]*" for failure to provide an application—indeed as the "only" one. 35 U.S.C. § 271(e)(4) (emphasis added). The fact that "the remedies provided under section 271(e)(4) are remedies for * * * infringement and not for a failure to provide the information required under subparagraph 262(*l*)(2)(A)" (Cross-Pet. 37) is a feature, not a defect. The exclusive focus on patent infringement is entirely consistent with the statutory design; the statute provides no basis for imputing additional remedies as a matter of California law. As Judge Chen correctly observed: "Entitled 'Patents,' § 262(*l*) of the BPCIA concerns one thing: patent litigation." Pet. App. 45a (Chen, J., dissenting).

Finally, even if Amgen were right that the court of appeals erred in determining that the BPCIA "expressly provide[s]" that its remedies are exclusive

within the meaning of California law such that it precludes a UCL remedy, correcting that supposed error would not decide any federal question. As noted, Amgen waived the separate question of whether the BPCIA provides an implied federal right of action to enforce disclosure of the biosimilar application (although the Federal Circuit nevertheless went on to provide Amgen such a right of action with respect to the notice of commercial marketing). Under federal law, implication of such a private right of action can be foreclosed even absent an express statement of exclusive remedies like the one in 35 U.S.C. § 271(e)(4). *See Touche Ross & Co. v. Redington*, 442 U.S. 560, 571 (1979) (rejecting argument that right of action should be inferred because "Congress did not express an intent to deny a private cause of action"). Without evidence of Congress's affirmative intent to *create* the right of action in question, such an action is unavailable—whether or not Congress included a statement expressly foreclosing added remedies. *See ibid.*; *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). Accordingly, the Federal Circuit's consideration in isolation of the exclusive remedies provision in Section 271(e)(4) for purposes of determining whether it precluded a UCL remedy provides a poor vehicle for consideration of any question of federal law.

2. *Amgen does not challenge the court of appeals' affirmance of the dismissal of its California conversion claim, which is correct in any event*

The court of appeals likewise affirmed dismissal of Amgen's California conversion claim on two alternative grounds: (1) Amgen failed to establish that Sandoz's withholding of its application was a "wrongful act" and (2) given the BPCIA's authorization of an applicant's use of "'publicly-available information' regarding the reference product in its application" and the expiration of Amgen's twelve-year exclusivity period, Amgen "fail[ed] to show that it has an *exclusive* right to possession of its approved license on Neupogen to sustain its claim of conversion under California law." Pet. App. 29a.

Amgen's cross-petition does not appear to challenge the court of appeals' affirmance of dismissal of its conversion claim at all, much less specifically allege error with respect to the alternative holding on Amgen's lack of an "exclusive right" under California law. Even if Amgen had attempted to challenge this aspect of the judgment, it would have provided no basis for review. The court of appeals' decision is correct, and, in any event, this Court need not grant certiorari to address the elements of a California claim for conversion.

Moreover, there are additional alternative state law grounds to affirm dismissal of Amgen's conversion claim. *See* Sandoz CA Br. 57-58. In particular, Amgen

has not properly pleaded conversion of an intangible property right under California law. The "work that Amgen did to obtain [its] license" (Amgen CA Br. 60) is not a property "interest capable of precise definition." *Alderson v. United States*, 686 F.3d 791, 796 (9th Cir. 2012). Further, California courts have consistently rejected theories that seek to expand conversion law where, as here, the proposed expansion would (1) interfere with the balance struck by a statute, such as the BPCIA, between the interests of the putative owner of intangible property rights and the interests of the public in the availability of important products and technologies; or (2) create an end-run around the requirements of patent law. *See Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 487-97 (Cal. 1990).

3. Sandoz's counterclaims provide no basis for review of Amgen's abstract BPCIA arguments

Amgen may contend on reply that the declaratory judgment entered in favor of Sandoz on Sandoz's counterclaims seeking an interpretation of the BPCIA (Pet. App. 31a, 83a; CA JA A22) presents federal questions that provide a vehicle for this Court's review. That would be incorrect; that judgment cannot be separated from Amgen's flawed state law claims.

As Sandoz explained when it first asserted its declaratory judgment counterclaims, they were relevant to the "disagreement between Amgen and Sandoz" only because "[i]nterpretation of the BPCIA would resolve

Amgen's claims for conversion and violation of California's Unfair Competition law." CA JA A281 (Sandoz Counterclaims ¶ 29). Indeed, Amgen in its answer to the counterclaims stated that they failed to state a claim "because they are merely defenses directed at an element of [Amgen's] claims, and are not proper counterclaims." Dist. Ct. Dkt. No. 28, Plaintiffs' Answer to Defendant Sandoz Inc.'s Counterclaims and Affirmative Defenses at 9 (Second Affirmative Defense).

The lower courts' disposition of Sandoz's counterclaims cannot be reviewed in isolation because they do not rest on any federal cause of action. *See Harris Cty. v. MERSCORP Inc.*, 791 F.3d 545, 552 (5th Cir. 2015) ("[T]he Declaratory Judgment Act alone does not create a federal cause of action."). A declaratory judgment action may be pursued only when "'a coercive action' brought by 'the declaratory judgment defendant,'" here Amgen, "'would necessarily present a federal question.'" *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 848 (2014) (quoting *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 19 (1983)). If the declaratory judgment defendant would have no cause of action to bring such a coercive action—as Amgen would not here because of its waiver of any federal cause of action and the state law defects in the causes of action it did pursue—a declaratory judgment action may not proceed on its own. Accordingly, if the Court does not review and overturn the Federal Circuit's conclusions that Amgen's affirmative claims fail as a matter of California law, the Court's review of the lower courts'

disposition of Sandoz's counterclaims would yield only an advisory opinion on an abstract question of statutory interpretation.

CONCLUSION

The conditional cross-petition for a writ of certiorari should be denied.

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